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August 21, 2000

The Honorable Carol Browner
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator Browner:

The following comments are submitted on behalf of People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, Physicians Committee for Responsible Medicine, and Earth Island Institute. These animal protection and environmental organizations have a combined membership of more than nine million Americans concerned with the suffering of animals used in laboratories.

GENERAL COMMENTS

The Environmental Protection Agency (EPA) letter to HPV chemical testing participants dated October 14, 1999 (based upon a negotiated agreement between the EPA, industry, the Environmental Defense Fund, and animal protection representatives) states in part:

"1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is significant data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.

8. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant."

We are therefore deeply concerned that the first two test plans submitted, for petroleum coke and aminosilanes, have ignored these instructions to a significant degree. The agglomeration of individual substances into categories is an important issue. The boundaries of any category are, to a large degree, arbitrary and dependent on the specific information and values that decision-makers in industry and government consider in moving forward. This variability exacerbates the animal protection community's concern that animals will suffer and die in HPV chemical tests that could easily have been avoided. When a reduction in the use of animals is not a primary focus of the

entire program (as it clearly is not), industries and/or companies will base their submitted categories on their own specific experiences. For example, the American Petroleum Institute (API) has submitted petroleum coke without considering coal coke, or even other carbon-based solid organic mixtures that might be created by or used in the tire and rubber, plastics, steel, utility, or gold-mining industries.

If the EPA's commitment to reducing the use of animals in the HPV program is to be more than lip service, cross-industry fertilization is essential in creating an efficient program. Because each industry will want to optimize tests for its specific product, there is little incentive for creating coherent test plans across industries. This fact clearly demonstrates a major flaw of the HPV program. The responsibility for being proactive in this arena lies with both industry and with the EPA – the agency that created the HPV program, that demanded massive numbers of animal tests, and that must ensure adherence to the principles set forth in the October 14, 1999, agreement. We are asking for a response from the EPA, as well as from API and the Silicones Environmental Health and Safety Council, regarding how they plan to enhance inter-industrial approaches to minimize overall testing and limit the number of animals killed in this program.

A careful analysis of the first two categories further reveals that the testing proposed will not serve any effective purpose in protecting the public or the environment but merely serves to "check the box" – an approach specifically ruled out by the October 14, 1999, agreement. Our specific comments on the first two submitted HPV test plans are attached and, in addition to the response requested above, we also look forward to a specific response to each of these concerns. I can be reached at (757) 622-7382, ext. 304, by e-mail at jessicas@peta-online.org. Correspondence should be sent to my attention at the following address: 4800 Baseline Road, #E104-390, Boulder, CO 80305.

Sincerely,

Jessica T. Sandler
Federal Agency Liaison

cc: The Honorable Robert C. Smith
The Honorable F. James Sensenbrenner, Jr.
The Honorable Ken Calvert
The Honorable Jerry F. Costello
Council on Environmental Quality

Comments on the Aminosilane Grouping and Test Plan

Comments on the Grouping of Aminosilanes

The Silicones Environmental, Health and Safety Council (SEHSC) has sensibly grouped two very similar aminosilane compounds into a single test plan. Chemically, these two compounds are very similar, and when released into the environment, they will rapidly degrade to nearly identical products. However, when these products enter into any relevant environmental setting, they will quickly react with water to hydrolyze to the trisilanol derivatives. Therefore, the potentially toxic moieties associated with the release of these compounds are the trisilanol derivatives or the degradation products of the trisilanols which are fairly unstable themselves. We suggest that a larger group be developed based on the chemical instability of silanes, with a focus of what potential toxic moieties really occur. Furthermore, toxicity data on these compounds may already exist, or these hydrolysis products may be included in other groupings of HPV chemicals. For example, further hydrolysis of these two compounds could result in the production of ethylenediamine or other alkyl amines, which are well characterized and would easily be included in an alkyl-amine group. This sort of consideration has been used in the development of the silane,[3-(2,3-epoxypropoxy)propyl]trimethoxy group submitted by SEHSC, where the environmental fate has dictated that almost no testing is deemed necessary.

Grouping based on the relevant toxic moiety will require the sponsoring organization of each group and the EPA to creatively consider the environmental fate of compounds in the environment and in organisms before embarking on testing. It may be necessary to revisit groupings to ensure that groups are characterizing all the relevant compounds. For example the sponsors of this group would need to ensure that the amine hydrolysis products of these silanes are addressed in any alkyl amine group.

Comments on the Aminosilane Test Plan

The dominant characteristics of the aminosilanes are their instability in water, which is referenced in the background information in the test plan. As water is one of the essential ingredients of all living things, any relevant environmental exposure will result in hydrolysis and degradation of the compounds. In looking at the test plan, SEHSC has done a relatively good job of considering the existing data in refining their test matrix. However, the SEHSC still plans to conduct repeat dose toxicity testing and reproductive toxicity testing, despite the fact that the aminosilanes are highly instable in environmental systems, with the test compounds essentially behaving like closed system intermediates. It should be noted that point no. 7 of the October 14, 1999, letter states that “participants shall not develop sub-chronic or reproductive toxicity data for the HPV chemicals that are solely closed system intermediates, as defined by the OECD/SIDS guidelines.” Clearly, this exclusion is due to lack of exposure to these materials and is similar to the situation with the aminosilanes.

We urge that the category be expanded to include the trisilanol compounds and perhaps other silanes that will rapidly degrade in water before considering conducting further toxicity testing. In addition, the stability of the trisilanols needs to be considered as well, so that the essential potentially toxic moieties may be identified before proceeding with these tests. The reproductive and repeat dose tests will be an irrelevant waste, as the compound administered to animals would immediately transform to other compounds that would potentially affect the animals. It is critical that these hydrolysis considerations be well understood before embarking on these testing plans, so that the focus of any evaluation is on the actual compounds that may potentially affect organisms, not their industrial precursors that immediately disappear upon administration in a test.

Therefore, we urge that the repeat dose toxicity and reproductive toxicity tests not be conducted on these compounds, as they will never be present in their industrial form in the environment or in organisms. Characterization of repeat dose and reproductive exposure should focus on the hydrolysis products of these compounds, which would be their true environmental occurrence. Tests should not be conducted on their environmentally unrealistic industrial formulation.

Conclusions

The aminosilane group is an obvious grouping of two very similar compounds that are dramatically unstable in environmental systems as they react immediately with water. This group should be expanded to include other silanes and degradation products as the environmental and biochemical effects rapidly transform these compounds to other byproducts. Potential toxicity should only be characterized using the actual compounds that affect organisms, not the industrial precursors.